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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,949	08/10/2000	Richard A. Shimkets	15966-559 (CURA-59)	5151

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EXAMINER	
SNEDDEN, SHERIDAN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/635,949	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4. 29 and 32, drawn to a polypeptide of a particular SEQ ID NO, classified in class 530, subclass 350+.

II. Claims 5-14, 30 and 33, drawn to a nucleic acid of a particular SEQ ID NO, a vector and host cell, classified in class 435, subclass 320.1.

III. Claims 15-17, 31 and 34, drawn to an antibody, classified in class 530, subclass 387.1 or 388.1.

IV. Claims 18 and 38, drawn to a method of determining the presence of a polypeptide, classified in class 435, subclass 7.1.

V. Claims 19 and 39, drawn to a method for determining the presence or amount of a nucleic acid, classified in class 435, subclass 6.

VI. Claim 20, drawn to a method of identifying an agent that bind to a polypeptide, classified in class 435, subclass 7.1.

VII. Claim 21, drawn to a method of identifying an agent that modulates the expression of a polypeptide, classified in class 435, subclass 7.1.

VIII. Claim 22, drawn to a method of modulating the activity of a protein, classified in class 435, subclass 7.1.

IX. Claims 23-24 and 40, drawn to a method of treating a PROX-associated disorder with a protein, classified in class 514, subclass 2.

X. Claims 25-26, drawn to a gene therapy method of treating a PROX-associated disorder with a nucleic acid, classified in class 424, subclass 185.1.

XI. Claims 27-28 and 41, drawn to a method of treating a PROX-associated disorder with an antibody, classified in class 424, subclass 185.1.

XII. Claim 35, drawn to a method of making a medicament, classified in class 514, subclass 1.

XIII. Claims 36-37, drawn to a method of screening for a modulator of activity or of latency or predisposition to a PROX-disorder, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of invention II are related to the protein of invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay. Thus, they can be unconnected in use and operation.

The protein of invention I are related to the antibody of invention III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric interaction of the two, they are distinct inventions because the primary sequence of the one is totally independent of the other. Additionally, the

protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of invention II and the antibody of invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

Inventions IV-V disclose a methods for detecting the products of invention I-II and are thus related. However, the inventions are patentably distinct because the product of inventions I or II need not be present during the detection process and thus the methods of inventions IV or V can neither utilize the products of inventions I or II nor be used to make such products.

Invention I is related to inventions VI-IX and XII-XIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein of invention I can be used to make the antibody of invention III or in any one of the methods VI-IX and XII-XIII. Thus, invention I is patentably distinct from the methods of inventions VI-IX and XII-XIII.

Invention II is related to inventions X and XII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid of invention II may be used in several in vitro processes, *e.g.* PCR reactions, sequencing methods, hybridization methods, or in the method of invention XII, for example. Thus, invention II is distinct from invention X and XII

Invention III is related to inventions XI and XII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of invention III may be used in several in vitro processes, e.g. purification methods, detection methods, or a method of making an anti-idiotypic antibody, or in the method of invention XII, for example. Thus, invention III is distinct from the inventions XI and XII.

The product of invention I is not used in the methods of inventions X and XI. Therefore, invention I are patentably distinct from invention X and XI.

The product of invention II is not used in the methods of inventions IV, VI-IX, XI or XIII. Therefore, inventions XVIII and I are patentably distinct from inventions IV, VI-IX, XI or XIII.

The product of invention III is not used in the methods of inventions IV-X and XVI. Therefore, invention III is patentably distinct from inventions IV-X, and XIII.

The methods of inventions IV-IX and XII-XIII require different products (*i.e*, protein, nucleic acid or antibody), different steps (*e.g., in vitro* vs. *in vivo*), and/or have different endpoints (*e.g.,* screening, identifying, treating, etc.). Therefore, inventions IV-IX and XII-XIII are patentably distinct one from another.

3. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Groups II-XIII, restriction for examination purposes as indicated is proper.

4. Additionally, each of inventions I through XIII are directed to patentably distinct and/or independent peptides (or use thereof), or nucleic acids encoding same, or antibody to same. Absent factual statement/evidence to the contrary, each different peptide sequence and/or polynucleotides sequence encoding same is considered distinct and/or independent, one from the other on the basis of physical, chemical and biological properties and function(s). Thus, when any one of the inventions I through XIII are elected under 35 USC 121, an additional election under 35 USC 121 is also required as to the elected peptide (by SEQ ID NO).

Applicant is advised that a reply to this requirement must include an identification of the peptide or nucleic acid that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election requirement is not to be construed as a species election, as these compounds do not share a common primary structure and appear to be patentably distinct.

Should applicant traverse on the ground that these different compounds are not patently distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

5. Claim 35 of the above invention XII recites a Markush group. As each recited therapeutic of the Markush group is patentably distinct, and each is structurally and functionally distinct, claim 35 will be examined solely for the elected subject matter. Restriction is proper as a search required for one is not required for another (see above discussion of the are patentable distinctness of each product).

Advisory Information

6. A telephone call was made to Ivor Elrifi on September 30, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
September 30, 2002

SKS

CHRISTOPHER S F LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600